UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PETER G. ANGELOS,

Plaintiff,

-against-

TOKAI PHARMACEUTICALS, INC., JODIE POPE MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BABERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C., and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

ECF Case: 1:17-cv-11365-MLW

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

Plaintiff, PETER G. ANGELOS ("Angelos"), by and through his undersigned attorneys, as and for his Complaint against Defendants alleges as follows:

INTRODUCTION AND INITIAL PUBLIC OFFERING ("IPO"), SUMMARY

1. On September 16, 2014, Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), a developmental stage pharmaceutical company, raised approximately $100 million in an initial public offering ("IPO") to conduct a Phase 3 trial. On June 24, 2015, with fanfare, it announced that the "pivotal" Phase 3 trial had begun and made multiple positive statements about the effectiveness of the drug thereafter. Repeated disclosures followed implying that the Phase 3 trial was proceeding on plan. A year later, on July 26, 2016, Tokai announced that the trial failed.

2. Defendants will demur, claiming "we disclosed that the trial might fail." They cannot fall back on this excuse. First, the Registration Statement was negligently written and did not disclose that the trial could not have been successful as designed. It omitted current material facts about unreliable preliminary data, the candidate drug's past test results and the design of

future tests to get "fast track" FDA approval, as well as conflicts of interest on the part of researchers. Second, soon after the IPO, when it became apparent that a sufficient number of test subjects could not be enrolled, management resorted to fraudulent practices. They misstated the number of test subjects to the public through the SEC and NIH, misstated the exclusion criteria to the NIH, and engaged in insider trading. In an effort to conceal the fraud from investors, Tokai never provided the reason for the Phase 3 trial's failure; instead, a year later, a specialized medical journal disclosed that there were only four, rather than 148, test subjects at the study's halt.

3. Tokai, its management, and its investment bankers falsely stated that the company had a promising drug candidate for the treatment of prostate cancer in patients with a specific genetic make-up. Receiving approval of the Food and Drug Administration ("FDA") and bringing this drug candidate to market was critical to Tokai's viability, because it only had one drug candidate "in the pipeline" for FDA approval and was running low on cash reserves.

4. Tokai's thesis to investors, disclosed in the first five pages of the Registration Statement, was that prostate cancer is the second most common form of cancer in men (after skin cancer). The two incumbent medications for prostate cancer were ineffective in a subset of patients with a specific genetic make-up, known as "AR-V7." However, the Company's Phase 2 trial of its drug candidate had shown effectiveness in four out of four patients with the AR-V7 gene (later, six out of seven, with one patient leaving the study for unrelated reasons). The Registration Statement stated that the two incumbent medications each had annual sales of $1.7 billion and $445 million. According to the Registration Statement, the Company would seek fast track approval from the FDA for a "pivotal" Phase 3 study of up to 177 patients with the AR-V7 gene.

5. For over a year, starting on June 24, 2015, the investing public thought that a substantive Phase 3 trial was underway in a study of 148 AR-V7 patients (reasons for the stated reduction to 148 from 177 patients are unclear). For example, the August 3, 2015 edition of the *Boston Business Journal* reported, "[t]hat 148 patient Phase III trial is underway, with results expected late next year, said [Tokai President and C.E.O.] Morrison." Investors based their false belief on the Registration Statement, Prospectus and subsequent disclosures by the Company that the study had 148 test subjects. Tokai never corrected its prior statements. In July 2016, the Company suddenly announced, without further explanation, that it had discontinued the Phase 3 trial based upon recommendation of the trial's independent Data Monitoring Committee. Even then, the Company concealed that Phase 3 trial had been discontinued *for lack of test subjects*. When the Phase 3 trial was halted, the study did not have 148 test patients—but only four.

6. Upon this announcement, the Company's shares lost most of their value. Angelos, who had bought shares shortly after the IPO, but made the majority of his investment after the announcement of the Phase 3 trial, lost over $10 million.

7. On August 22, 2016, in a Form 8-K filed with the SEC, Tokai stated that it has determined to discontinue enrollment in its Phase 3 clinical trial of galeterone and not to proceed with its planned study of the drug.

8. Tokai shares traded on the NASDAQ under the symbol "TKAI." On or about May 11, 2017, after a corporate combination, the name of the surviving corporation was changed to Novus Therapeutics, Inc. The Company's common stock remains listed on the NASDAQ, under the new name as of May 11, 2017. The trading symbol also changed on that date from "TKAI" to "NVUS."

9. The reason for the trial's failure is simple and must have been known to Tokai and its management before July 26, 2016—lack of test subjects. The reason for the study's halt did not become public until June 7, 2017, when the American Society of Clinical Oncology ("ASCO") disclosed that the study had only 38 patients as test subjects when the study was halted. Of those, 35 patients "screen failed" (which means they did not meet the eligibility criteria to remain in the study), and four were "discontinued at study halt." Significantly, the Company mislead investors into believing there were 148 viable test subjects, when in fact, there were only four.

10. The Company and its agents (including senior management and investment bankers) made other material misstatements and omissions of fact:

a. They overstated the percentage of patients having the AR-V7 gene variant among prostate cancer patients.

b. They omitted to state that the studies showing the ineffectiveness of the incumbent medications in AR-V7 patients were not reliable, and that fact was even admitted by the leaders of those studies.

c. Although they disclosed that the two incumbent medications had annual sales of $1.7 billion and $445 million, they failed to disclose that the clinical studies supporting FDA approval of those medications involved 1,195 and 1,199 test patients, respectively (versus a putative 148 test patients).

d. Of conclusions that could be drawn from the Phase 3 study, an undisclosed finding was that the incumbent medications were actually more effective than the Company's drug candidate for treating AR-V7 patients.

e. They did not disclose that six of the eight scientists touting the effectiveness of the drug candidate in the Phase 2 studies in the May 2016 *Journal of Oncology* article had financial connections to the Company.

f. They did not disclose that both Co-Principal Investigators running the Phase 3 trial had financial connections with the Company.

g. They did not accurately disclose the Company's communications with the FDA. These communications included the negotiation of exclusion criteria which were so limiting that it was not possible for Tokai to enroll an adequate number of test subjects.

11. Evidence of scienter permeates the IPO and subsequent disclosures:

a. The Company *never* disclosed that the Phase 3 Study failed for lack of test subjects. A specialized medical journal did.

b. The Company repeatedly made misleading submissions to the public on a web-site sponsored by the National Institutes of Health, www.ClinicalTrials.gov. First, before the Phase 3 was halted, the Company repeatedly stated that it anticipated 148 test subjects, when in fact, the largest number of subjects ever enrolled in the Phase 3 trial was 38.

c. Second, the Company listed on www.ClinicalTrials.gov only two of multiple exclusion criteria that caused 34 of the 38 test subjects to "screen fail" when the Phase 3 trial was halted.

d. Insider selling of the Company's shares was rampant, including the C.E.O., C.F.O., C.O.O, and a venture capital fund connected to one of the Company's Directors.

12. A public investor, like Angelos, would not learn of these misstatements and omissions in the course of ordinary due diligence. For example, it was necessary to cross reference multiple, specialized medical journal articles to unearth the financial connections between the Company and the scientists who promoted Tokai's drug candidate.

13. As a result of Defendants' misleading statements and omissions, Angelos lost over $10 million. By contrast, Tokai's insiders averted losses by virtue of their inside roles.

JURISDICTION AND VENUE

14. The claims asserted herein arise under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 771(a)(2) and 770 and under Sections l0(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a) and Rule l0b-5 promulgated thereunder. Jurisdiction is conferred by Section 22 of the Securities Act and Section 27 of the Exchange Act.

15. Venue is proper in the District, where Tokai had its principal places of business at 255 State Street, Boston, MA and One Broadway, Cambridge, MA; where the Defendants conducted business or reside; and where the materially false and misleading Registration Statement and other documents complained of herein were prepared and disseminated.

THE PARTIES

16. Angelos, a resident of Maryland, purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby. Attached as Exhibit A is a summary of Plaintiff's purchases, sales, and losses, which exceed $10 million, in connection with Tokai common stock.

17. Tokai was a Delaware Corporation, incorporated in 2004.

18. Defendant Jodie P. Morrison ("Morrison") is and at all relevant times was the Company's President and Chief Executive Officer and signed the Registration Statement. Morrison also

signed and certified the Form 10-K, Annual Report, on March 10, 2016. All of these documents filed with the SEC contained materially false and misleading information. Between June 25, 2015 and July 29, 2015, Morrison sold roughly 28,564 shares of Tokai stock, for approximately $393,000.

19. Defendant Lee H. Kalowski ("Kalowski") was Tokai's Chief Financial Officer from September 2014 until his resignation on August 31, 2016. He signed the Registration Statement, Quarterly Reports (Form 10-Q) and Annual Report (Form 10-K), certifying that the 10-K was accurate pursuant to the Sarbannes-Oxley Act. All of these documents filed with the SEC contained materially false and misleading information. During the relevant time period, Defendant Kalowski sold thousands of shares of Tokai stock.

20. Defendant Seth L. Harrison ("Harrison") was at all relevant times Tokai's Chairman. He signed the Registration Statement using Defendant Morrison as his Power of Attorney.

21. Defendant Timothy J. Barberich ("Barberich") was at all relevant times a Company director. He signed the Registration Statement using Defendant Morrison as his Power of Attorney.

22. Defendant David A. Kessler ("Kessler") was at all relevant times a Company director. He signed the Registration Statement using Defendant Morrison as his Power of Attorney.

23. Defendant Joseph A. Yanchik, III ("Yanchik") was at all relevant times a Company director. He signed the Registration Statement using Defendant Morrison as his Power of Attorney.

24. Defendant BMO Capital Markets Corp. ("BMO") is a financial services company with principal executive offices located at 3 Times Square, New York, NY 10036.

25. Defendant Stifel, Nicolaus & Company ("Stifel") is a financial services company with principal executive offices located at 501 N. Broadway, St. Louis, MO 63102.

26. Defendant William Blair & Company, L.L.C. ("William Blair") is a financial services company with principal executive offices located at 666 Fifth Avenue, New York, NY 10103.

27. Defendant Janney Montgomery Scott LLC ("Janney") is a financial services company with principal executive offices located at 1717 Arch Street, Philadelphia, PA 19103.

28. Defendants Morrison, Kalowski, Harrison, Barberich, Kessler and Yanchik are referred to herein as the "Individual Defendants."

29. Defendants BMO, Stifel, William Blair and Janney (the "Underwriter Defendants") are named as defendants herein for the claims arising under the Securities Act. They were the underwriters of the IPO, assisting in the drafting and dissemination of the offering documents and the sale of the Company's IPO shares to the investing public.

Other Parties

30. Non-party Dr. Campbell Murray ("Murray") was a director of Tokai from May 2009 until September 2014, right before the IPO. Murray is also the Managing Director of Novartis Venture Fund (a/k/a Novartis BioVentures Ltd.) ("Novartis"), and has been since August 2005. Dr. Reinhard J. Ambros, another former Tokai Board member, was an employee of Novartis at the time of the IPO. The Registration Statement/Prospectus noted that "upon the closing of this offering, our two largest stockholders, Apple Tree Partners and Novartis BioVentures, will beneficially own shares representing approximately 36.68% and 21.25% of our common stock, respectively . . . . Each stockholder acting individually, as well as together, will exercise significant control over our management and affairs." Between June 11, 2015, and July 15,

2015—only weeks into the Phase III trial—Novartis sold roughly 85,952 shares of Tokai stock, for approximately $1,241,000.

SUBSTANTIVE ALLEGATIONS

31. According to the *Boston Business Journal* (Aug. 3, 2015), Tokai changed its focus in 2008 to develop a medication for prostate cancer. The Company's sole drug candidate was "galeterone," a proposed product that was in various clinical trials for the treatment of patients with metastatic castration-resistant prostate cancer ("CRPC" or "mCRPC") with a specific genetic trait called "AR-V7."

32. At all relevant times, Tokai had no other drug proposed for FDA approval and generated no revenues. At December 31, 2013, Tokai had negative cash flows, an accumulated deficit of $63 million, and cash reserves to remain in operation for approximately one year. Therefore, a successful IPO was critical to Tokai as a going concern.

33. Tokai's IPO was made pursuant to a negligently false and misleading Registration Statement on Form S-1A (the "Registration Statement"), dated September 2, 2014, and Prospectus filed pursuant to Securities Act Rule 424(b)(4) on September 18, 2014 ("Prospectus"). On September 16, 2014, the U.S. Securities and Exchange Commission ("SEC") declared the Registration Statement effective, and on September 18, 2014, Tokai's investment bankers priced the shares, filed a final Registration Statement, and commenced the IPO, by which the Company raised $105.3 million.

A. FDA Approval Process for Drug Candidates

34. As a general rule, it is unlawful for a pharmaceutical company to sell a drug without FDA approval.

35. The First Circuit has described the three phases of clinical trials of a candidate drug to receive FDA approval:

- Phase 1 clinical trials, generally conducted on 20 to 80 healthy volunteers to determine how the drug works in humans;

- Phase 2 clinical trials, generally involve no more than several hundred subjects and are designed to evaluate the effectiveness of the drug, as well as short-term side-effects; and

- Phase 3 clinical trials, generally involve several hundred to several thousand subjects and are designed to gather information necessary to provide a basis to label the drug.

See N.J. Carpenters Pens. & Ann. Fund v. Biogen Idec, Inc., 537 F.3d 35, 39 (2008).

36. As set forth herein, the Phase 2 and 3 clinical trials of galeterone severely digressed from the standards for clinical trials set forth in regulations administered by the FDA, as observed by the First Circuit.

B. Tokai's Registration Statement

37. The Registration Statement stated that galeterone is "a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies."

38. The Registration Statement stated the Phase 3 trials would focus on patients with DNA exhibiting "truncated androgen receptors as having C-terminal loss," the most common variant of which is called "AR-V7."

1. Misleading Statement About Preliminary Data

39. The Registration Statement continued, "[i]n clinical studies conducted by researchers at MD Anderson Cancer Center and Johns Hopkins University, the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga® . . . and Xtandi® . . . two of the highest selling therapies for CRPC with aggregate worldwide 2013 sales of more than $2.1 billion" (hereinafter, collectively "Incumbent Prostate Medications").

40. This disclosure about Incumbent Prostate Medications is misleading. It does not explain that the leaders of each of these clinical studies freely admitted that the studies were not reliable. Dr. Eleni Efstathiou wrote, "limited patient numbers warrant further validation."[1] About the other study, Dr. Emmanuel S. Antonarakis stated, "[n]ow that was a small pilot trial for about 62 patients. We have subsequently expanded the study. . . ."[2]

2. Misleading Statement About Discussions with FDA

41. The Registration Statement also said that going forward, Tokai would:

> Complete the clinical development of and seek marketing approval for galeterone for the treatment of CRPC patients with prostate cancer tumors that express the AR-V7 splice variant. Based on discussions with the FDA, we expect that our ARMOR3-SV (Phase 3) trial will be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naive patients whose prostate tumors express the AR-V7 splice variant. We expect to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016.

42. This statement about the Company's "discussions with the FDA." was materially false and misleading As set forth in further detail below, it omitted to disclose that the discussions with the FDA included exclusion criteria for test patients enrolled in Phase 3 that were so restrictive that out of 973 enrolled test patients, only four patients did not screen fail when Phase 3 was halted.

3. Misleading Statement About Incumbent Prostate Medications

[1] U.S. Department of Health and Human Services Author Manuscripts available on the National Institutes of Health web site: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4247811/

[2] Transcript of streaming video statement available at http://www.onclive.com/insights/prostate-cancer-testing/johns-hopkins.

43. The Registration Statement then provides an investment thesis which is misleading. It stated that prostate cancer is the second leading form of cancer in men (after skin cancer), that the American Cancer Society estimates that there will be 233,000 new cases diagnosed in 2014, and 29,000 men will die of the disease. The Registration Statement then dangles the bait with respect to the Incumbent Prostate Medications: "with reported worldwide 2013 sales of $1.7 billion for Zytiga and $445 million for Xtandi."

44. These statements about the financial success of the Incumbent Prostate Medications are misleading in light of the omitted information that Zytiga's trial had 1,195 test patients and Xtandi had 1,199 test patients, when the proposed Phase 3 called for only 177.

4. Misleading Statements about Conflicted Researchers

45. The Registration Statement disclosed select results of the Phase 2 clinical trials on AR-V7 patients that were astounding. The Company stated that in "May 2014, we announced interim data from our ARMOR2 trial at the Annual Meeting of the American Society of Clinical Oncology or ASCO. . . . In addition, we presented data from a retrospective subset analysis in which four treatment-naïve CRPC patients in ARMOR2 (Phase 2) were identified as having truncated androgen receptors with C-terminal loss. All four of these patients had maximal reductions in PSA levels of at least 50%." A reduction in PSA levels means that a cancer patient is recuperating.

46. The disclosure about the Phase 2 results was misleading in several ways. As a threshold matter the ASCO Meeting Library abstract for the Tokai presentation on May 31, 2014, makes no reference to a retrospective subset analysis of four AR-V7 patients.[3]

[3] *See Galeterone in Men with CRPC: Results in Four Distinct Patient Populations form the ARMOR2 Study,* available at https://meetinglibrary.asco.org/record/93499/abstract

47. The presentation was made by Dr. Bruce Montgomery. Although Tokai discloses Dr. Montgomery's affiliation as "Professor, Medical Oncology Division, University of Washington School of Medicine and a lead investigator of ARMOR2," Tokai did not disclose Dr. Montgomery's links to Tokai. In fact, Dr. Montgomery had a financial relationship with Tokai, according to a specialized medical article unrelated to the IPO.[4]

48. Furthermore, while the Registration Statement reported that "a retrospective subset analysis" led to optimal results, specifically that "[a]ll four of these patients had maximal reductions in PSA levels," they failed to disclose that the individuals conducting this study also had ties to the Company. An article from an independent journal published this information a year and a half after the IPO, noting that six of the eight scientists reporting the near 100% effectiveness of galeterone in AR-V7 patients had financial affiliations with Tokai.[5] The authors and their Tokai affiliations are:

a. Mary-Ellen Taplin – Honoraria, travel, accommodations and expenses provided by Tokai;

b. James Cochran – Research funding provided by Tokai;

c. Karen Ferrante – Employed by Tokai, and ownership interest in Tokai;

d. Jennifer Roberts – Employed by Tokai and ownership interest in Tokai; and

e. Oliver Sartor – Consulting and advisory role with Tokai, and research funding provided by Tokai.

49. Tokai did not disclose these, and other conflicts of interest on the part of the scientists overseeing the clinical trials for galeterone.

[4] *See Update on Clinical Trials in Metastatic Prostate Cancer*, available at http://www.ascopost.com/issues/november-10-2015/update-on-clinical

[5] *See Journal of the Clinical Oncology,* 34, no. 15-suppl (May 2016) 5064-5064.

5. Misleading Statements about Phase 2 Data and the Effectiveness of Galeterone

50. The Registration Statement contains inaccurate statements about the Phase 2 data and the effectiveness of galeterone in AR-V7 patients. The Registration Statement touted the effectiveness of galeterone, stating "[a]ll four of the patients had maximal reductions in PSA levels of at least 50%." However, after Phase 3 was halted, *The Journal of Clinical Oncology* reported the results of that trial.[6] Out of 953 patients that were screened from September 2015 to the study halt, only 38 patients with AR-V7 could be studied. Notwithstanding the fact that all but four ultimately "screen failed" (they did not meet the eligibility criteria to remain subjects in the study), 19 patients were administered galeterone, and 19 were administered Xtandi. At the study halt, only 13% of the galeterone patients reduced their PSA levels by 50%, but 42% of the Xtandi patients reached that same mark—precisely the opposite results of the Phase 2 study reported in the Registration Statement.

51. The results of the Phase 3 trials also establish that the percentage of patients with the AR-V7 variant were inaccurate in the Registration Statement. The Registration Statement disclosed that in the Phase 2 trial, there were 51 evaluable patients, of which, there were seven patients having C-terminal loss. There were 23 testing locations in the United States and Canada.

52. The Phase 3 trial examined 953 patients, of which 38 exhibited AR-V7, the most common variant of C-terminal loss. There were 117 testing locations in the United States, Europe, Canada and Australia.

53. In Phase 3, 13.7% of the enrolled patients had C-Terminal loss (seven of 51), but only 3.9% for the Phase III Trial had the AR-V7+ variant (38 of 953). Therefore, the percentage of patients with AR-V7 was grossly inaccurate in the Registration Statement. Conversely, the

[6] *See* 35, no.15-suppl (May 2017) 5005-5005.

enormous number of enrolled test patients necessary to produce expected 177 patients with AR-V7 was omitted.

6. Failure to Disclose that Phase 3 Would Fail

54. The Registration Statement was false, notwithstanding the many warnings about what *could* occur in the Phase 3 trial of galeterone set forth in the Risk Factors section of the Registration Statement, because it did not disclose that galeterone had *no* reasonable chance of being approved by the FDA.

55. First, prior to the filing the Registration Statement, Tokai never conducted a Phase 2 trial designed to test the effectiveness of galeterone on AR-V7 patients. Nor did it run a comparative trial designed to test the drug's effectiveness against Zytiga and Xtandi. Instead, the Company merely ran a Phase 2 trial testing galeterone for effectiveness in CRPC prostate cancer, evaluating 51 treatment-naïve cancer patients classified as CRPC. For these reasons, Tokai lacked any reasonable basis to contend that galeterone is more effective, if at all, than Zytiga or Xtandi,

56. Aware that an article entitled "AR-V7 And Resistance To Enzalutamide And Abiraterone In Prostate Cancer," (the "NEJM Article") being prepared for publication in the New England Journal of Medicine would state that Zytiga and Xtandi were not effective in AR-V7 patients, Tokai conducted an after-the-fact analysis of the Phase 2 trial and did a so-called "retrospective subset analysis," to be able to represent in the Registration Statement that Tokai's focus was on AR-V7; that four out of the 51 patients in the study had AR-V7; and that galeterone was effective in all four of those patients.

57. The NEJM Article was published in the *New England Journal of Medicine* on September 3, 2014 at NEJM.org. Tokai was aware of the upcoming publication of the NEJM

Article because one of its authors—Dr. Mario Eisenberger—was also a lead contributor on the galeterone Phase 2 trial.

58. That the material change of Tokai's business model was driven by the eminent publication of the NEJM Article is evident from a review of the Company's preliminary and final registration statements, each iteration placing greater and more frequent emphasis on AR-V7. Moreover, while the final Registration Statement said that galeterone was effective in six of seven AR-V7 patients, an earlier draft represented that only "four patients were identified as having altered androgen receptors that were truncated, all of whom showed clinically meaningful PSA reductions of at least 50%."

59. Accordingly, Tokai's business model, prospects and clinical trial results were materially revised shortly before the filing of the Registration Statement, in order to differentiate galeterone from existing products and induce investors to purchase Tokai shares. The Registration Statement failed to disclose that Tokai never conducted a Phase 2 trial designed to test the effectiveness of galeterone on AR-V7 patients; that the Company had materially changed its focus shortly before the IPO to focus on AR-V7 patients; that the six AR-V7 patients who showed improvement had very recently been only four; and that its so-called "test results" were actually predicated on a to-be-published NEJM Article. These facts were material to investors because they would have reasonably concluded that the Company was going public with no viable business plan.

60. Second, Tokai's design of galeterone's Phase 3 trial was flawed and virtually guaranteed to fail. Tokai was embarking on its Phase 3 trial blind, as no prior testing had been done to measure the drug's effectiveness in AR-V7 patients, and the very structure of its Phase 3 test was woefully inadequate.

61. As an initial matter, the FDA typically requires the successful completion of two well-controlled clinical trials involving 300 to 3,000 volunteers, to support approval. In the case of galeterone, however, Tokai planned only a *single* trial involving 170 patients. (For comparative purposes, the Phase 3 study size for Xtandi involved 1,199 patients; the study for Zytiga involved 1,195 patients).

62. To make matters worse, galeterone's Phase 3 trial was unprecedented, and Tokai had no reasonable basis to expect success. Tokai abandoned its Phase 2 trial design and formulated an entirely new trial design with two principal characteristics: (i) whereas the Phase 2 trial was evaluating galeterone as a stand-alone drug, Tokai designed its Phase 3 trial to compare galeterone specifically to Xtandi; and, (ii) whereas the Phase 2 trial used a decreased PSA level as an endpoint, Tokai changed its endpoint to be radiographic progression free survival ("PFS"). Thus, not only did Tokai change the very subject of the test, but also how success would be measured.

63. Tokai had no idea what outcome to expect from the Phase 3 trial since the test group and endpoint were so changed that it was as if no Phase 2 trial had ever been completed.

64. Because this was Tokai's first and only IPO, all shares purchased by Angelos are traceable to the IPO and Tokai's final Registration Statement filed with the SEC. Subsequent to the IPO, Tokai was a "public company" and its false and misleading statements and public filings about galeterone are actionable under the federal securities laws.

C. Tokai's Disclosures Subsequent to the IPO

1. Misleading Statements About Conflicted Researchers

65. On June 24, 2015, Tokai publicly announced commencement of the Phase 3 trials by issuing a press release entitled "Tokai Pharmaceuticals Announces Initiation of Phase 3

ARMOR3-SV Trial of Galeterone in AR-V7 Positive Metastatic Castration-Resistant Prostate Cancer." The press release stated, in part:

> ARMOR3-SV represents an important step forward in bringing precision medicine to patients with prostate cancer, and we are pleased with the progress made by our valued collaborator Qiagen in readying the AR-V7 clinical assay for global implementation," said Jodie Morrison, President and Chief Executive Officer of Tokai. "With worldwide commercial rights to galeterone, our pivotal clinical trial on track to read out by the end of 2016, and a strong financial position, Tokai is well positioned to realize its mission of bringing new therapeutic treatment options to patients with prostate cancer.
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> . . .
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> Based on the evidence reported thus far, a diagnostic tool that can predict patient responsiveness to certain therapies should lead to more informed treatment decisions and ultimately better care for prostate cancer patients," said Mary Ellen Taplin, M.D., Director of Clinical Research, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute and lead U.S. investigator of ARMOR3-SV. "Given the encouraging clinical data reported to date for galeterone and the precision medicine approach being employed in Tokai's pivotal trial, this study has the opportunity to alter the treatment landscape for metastatic CPRC patients."
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> . . .
>
> The company expects topline data from ARMOR3-SV to be available by the end of 2016.

66. The reference to Dr. Taplin being affiliated with the Dana-Farber Cancer Institute is misleading. As alleged above, the *Journal of Clinical Oncology* later disclosed that Dr. Taplin had extensive financial relationships with Tokai, including honoraria, a consulting or advisory role, and Tokai's payment of travel, accommodations and expenses.

67. The other co-principal investigator of Phase 3 was Dr. Montgomery, who also had an undisclosed financial relationship with Tokai, as alleged above.

68. The June 24, 2015, Press Release quotes Dr. Taplin stating that "[g]iven the encouraging clinical data reported to date for galeterone and the precision medicine approach being employed in Tokai's pivotal trial this study has the opportunity to alter the treatment landscape for

metastatic CPRC patients." The press release also states that Phase 3 "has been initiated in more than 15 sites in the United States. . . ."

69. Angelos read the press release and relied on it.

2. Misleading Statements About Preliminary Data

70. On January 12, 2015, Tokai issued a Press Release that reiterated prior false and misleading information. It stated retrospective analyses of tests at Sloan Kettering and MD Anderson have shown that AR-V7 "is associated with poor responsiveness to the Incumbent Prostate Medications. However galeterone was associated with clinical responses in six of seven patients with C-terminal loss." This statement is misleading, because it does not disclose that the leaders of those studies found them to be preliminary.

71. On or about August 28, 2015, Tokai issued a statement entitled "Unmet Need in CRCP Patients with C-Terminal Loss," explaining the efficacy of galeterone. Plaintiff relied on this statement. The release stated, "[i]nterim data from Tokai ongoing Phase 2 clinical trial of galeterone, ARMOR2, included seven patients who were identified as having altered androgen receptors that were truncated, six of whom shared clinically meaningful PSA reductions of at least 50 percent." This statement is misleading because it does not disclose that the leaders of these studies found them to be preliminary.

72. Angelos bought additional shares based upon these press releases.

3. Misleading Statements About Number of Test Subjects

73. Tokai's first public misstatement in an SEC Quarterly Report about the number of test subjects occurred in August 2015, less than three months after announcement of the Phase 3 trials. On August 12, 2015, Tokai filed a Quarterly Report on Form 10-Q with the SEC, stating in part:

> We have initiated our pivotal Phase 3 clinical trial of galeterone, which we refer to as ARMOR3-Splice Variant, or ARMOR3-SV, in metastatic CRPC patients whose tumor cells express AR-V7. In ARMOR3-SV, ***we are comparing galeterone to Xtandi® (enzalutamide) in 148 metastatic CRPC patients*** who have not received other second-generation oral therapies or chemotherapy for their CRPC. The primary endpoint of ARMOR3-SV is radiographic progression-free survival assessed by blinded independent central review. Selection of patients with AR-V7 is made using a clinical trial assay optimized for global use by our collaborator, Qiagen. Implementation of the clinical trial assay is ongoing and screening of eligible patients is expected to begin this quarter. The design of ARMOR3-SV is informed by feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency. We expect top-line data from ARMOR3-SV to be available by the end of 2016. We have been given fast track designation by the FDA for galeterone for the treatment of CRPC.

74. The Quarterly Report was signed by Defendant Kalowski, Tokai Chief Financial Officer.

Plaintiff relied upon the information in the Quarterly Report.

75. On August 3, 2015, the *Boston Business Journal* quoted Defendant Morrison as stating:

"That 148-patient Phase 3 trial is underway, with results expected late next year, Morrison said."

Plaintiff relied on this statement.

76. On August 12, 2015, Tokai also issued a press release entitled "Tokai Pharmaceuticals Reports Second Quarter 2015 Results." The press release stated, in part:

> Tokai's business highlights for the quarter include the initiation of ARMOR3-SV, Tokai's pivotal Phase 3 clinical trial of galeterone in men with metastatic castration-resistant prostate cancer (mCRPC) whose tumor cells express the AR- V7 splice variant, which is a truncated form of the androgen receptor that has been associated with non-responsiveness to commonly-used oral therapies for mCRPC.
>
> ARMOR3-SV is designed to evaluate whether administration of galeterone results in a statistically significant increase in radiographic progression free survival as compared to Xtandi® (enzalutamide) ***in 148 treatment-naive mCRPC patients whose prostate tumor cells express the AR-V7 splice variant.*** This trial represents the first pivotal trial in prostate cancer that employs a precision medicine approach for patient selection. The design and clinical rationale for ARMOR3- SV was presented last quarter at the 2015 Annual Meeting of the American Society for Clinical Oncology. Topline data from ARMOR3-SV are anticipated by the end of 2016.

. . .

> "We believe that AR-V7 positive metastatic CRPC represents a significant unmet market opportunity, and that ARMOR3-SV has the potential to change the treatment landscape for metastatic CRPC patients by enabling treating physicians to make more informed treatment decisions," said Jodie Morrison, President and Chief Executive Officer of Tokai. "We are pleased with our progress in initiating ARMOR3-SV globally, and with screening of patients beginning this quarter, we expect topline data from the study by the end of next year. With worldwide rights to galeterone and a pipeline of candidates from our ARDA discovery platform, a strong financial position and pivotal data expected next year, we are well positioned to create value from Tokai's pipeline and achieve our mission of developing and delivering innovative therapies that provide hope and healing for patients living with cancer."

(Emphasis added.)

77. The Quarterly Report was signed by Defendant Kalowski, Tokai Chief Financial Officer.

78. Tokai continued misrepresenting the number of test subjects. On November 10, 2015, Tokai filed a Quarterly Report on Form 10-Q with the SEC, stating, in part:

> We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in ***approximately 148 CRPC patients*** whose prostate tumors express the AR-V7 splice variant.

(Emphases added.)

79. The Quarterly Report was signed by Defendant Kalowski, Tokai Chief Financial Officer.

80. On March 10, 2016, Tokai issued a press release announcing its 2015 annual results. Defendant Morrison stated, "We have made substantial progress in the last several months, executing our Phase 3 ARMOR3-SV trail globally and expanding our galeterone development program to include additional underserved patient populations with prostate cancer." The press release continues that over 100 clinical sites in the United States, Canada, Australia and Western Europe are open and actively screening patients. These statements are misleading as the trial never had more than 38 enrollees and ended with only four.

81. On March 10, 2016, Tokai filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "2015 10-K"). In the 2015 10-K, Tokai stated, in part:

> We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in ***approximately 148 treatment-naive mCRPC patients*** whose prostate tumors express the AR-V7 splice variant.

(Emphasis added.)

82. The Annual Report was signed by Defendants Morrison, Kalowski, Harrison, Barberich, Kessler and Yanchik, and it was certified as accurate by Defendants Morrison and Kalowski pursuant to the Sarbannes-Oxley Act.

D. <u>Post-IPO Statements by Underwriter Defendants</u>

83. On October 13, 2014, Underwriter Defendant BMO issued a research report on Tokai. Plaintiff relied on this research report. The Research report reiterated many of the false statements made by the Company in the registration statement, periodic SEC disclosures and press releases. The report stated, in part:

> With 12% of the . . . treatment-naïve CRPC population expressing ARV7 mutation and not responsive to marketed drugs ZYTIGA and Xtandi, and with 67% of patients failing both ZYTIGA and XTANDI expressing ARV7 mutation, we believe that significant unmet need exists for a drug like galeterone with a unique triple mechanism of action, effects on androgen receptor degradation, and high response rate in patients harboring ARV7 mutation. Indeed, with a PSA50 response rate of 77% in treatment-naïve metastatic CRPC patients, comparable to ZYTIGA and XTANDI rates of 79% and 62%, and with 6/7 patients with ARV7 mutation demonstrating PSA response to galeterone, we believe that a sufficiently differentiated profile has emerged already to support superiority to XTNADI and establish dominant positioning beyond patients harboring ARV7 mutation.

84. On March 17, 2015, Underwriter Defendant William Blair issued a research report on Tokai that reiterated false and misleading information about the Company, upon which Plaintiff

relied. The report also states that "[b]oth Tokai and Quuigen have confirmed today that ARMOR3-SV is on track to start in first half of 2015."

85. The foregoing post-Registration Statement statements were materially false and/or misleading and failed to disclose that: (i) there were significant structural and other problems with the Company's ARMOR3-SV study trial design; (ii) Tokai was not able to recruit anything close to 148 viable test subjects; (iii) consequently, ARMOR3-SV would not succeed in meeting its primary endpoint; (iv) as a result, commercialization of galeterone was unlikely and/or imminent than Tokai had led investors to believe; and (v) as a result of the foregoing, the representations concerning Tokai's business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis.

E. Phase 3 Trial Halted

86. Given the significantly flawed, inadequate, and insufficient testing, galeterone had no reasonable chance of success. On July 26, 2016, only two and one-half months after assuring investors that Tokai had made "significant progress in our clinical development program for galeterone," that it had "continued to accelerate screening and enrollment," that it had "strengthened" its development team, and that it looks forward to "continued progress in the months ahead," according to Morrison in the Company's May 10, 2016 press release, Tokai announced the discontinuance of the Phase 3 trial following the recommendation made by the trial's independent Data Monitoring Committee on July 25, 2016. According to the Company:

> [T]he DMC determined that the ARMOR3-SV trial will likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival ("rPFS") for galeterone versus enzalutamide in AR-V7 positive mCRPC.

87. The Company essentially admitted that continuing the Phase 3 trial was futile.

88. Shortly after the discontinuance of the Phase 3 trial, Tokai announced in a Form l0-Q a reduction of approximately 60% of its workforce and stated that "there is a substantial likelihood that the Company will not pursue the development of galeterone in AR-V7 positive CRPC in the future."

F. Angelos Learns of the Deception

89. The Company's July 26, 2016, announcement caused the price of Tokai common stock to fall precipitously. The stock fell from a closing price of $5.20 on July 25, 2016, to a closing price of $1.10 on July 26, 2016, after Tokai publicly announced discontinuance of its Phase 3 trial.

90. Plaintiff sold the remainder of his holdings in Tokai after the Company's July 26, 2016 announcement at prices between $1.2027 and $1.0576 per share, a loss of well over 90%.

91. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff has suffered damages in excess of $10 million.

92. In May 2017, almost a year after the Phase 3 trial was halted, an article in the Journal of Clinical Oncology disclosed the reasons why.[7] The article states that 953 patients were screened for AR-V7 from September 2015 to study closure. Seventy-three men were AR-V7+ and 250 were AR-V7-, and 630 had no C-terminal loss (unevaluable). Among the AR-V7+ men, 38 were randomized (19 treated with galeterone and 19 treated with Xtandi). At study halt, "31 screen failed, and 4 were discontinued from screening at study halt." "PSA response rates in evaluable patients" were 2/16 (13% for galeterone), and 8/19 (42%) for Xtandi.

[7] *See Clinical factors associated with AR-V7 detection in ARMOR3-SV, a randomized trial of galeterone (Gal) vs. enzalutamide (Enz) in men with AR-V7+ metastatic castration resistant prostate cancer (mCRPC),* 35, no. 15_suppl (May 2017) 5005-5005.

93. Tokai never revealed this information any time during or after the halt of the Phase 3 trial.

LOSS CAUSATION

94. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff.

95. Plaintiff purchased Tokai's securities at artificially inflated prices and was damaged thereby. As alleged above, Plaintiff purchased securities that were issued on the basis of a negligently drafted Registration Statement and Prospectus. For these documents not to be misleading they would have to disclose that the Phase 3 trial would (not "could") fail and to disclose multiple omissions about the reliability of preliminary data, conflicted researchers and other material matters. Also alleged above, Plaintiff relied on multiple fraudulent statements about the number of test subjects in Phase 3, which were never corrected by Tokai. When Tokai announced that Phase 3 was halted, share price plummeted and Plaintiff was damaged thereby.

SCIENTER ALLEGATIONS (WITH RESPECT TO THE EXCHANGE ACT CLAIMS)

96. As alleged herein, Tokai, Morrison, and Kalowski acted with scienter in that they knew or were reckless in not knowing that: (i) the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; and (ii) such statements or documents would be issued or disseminated to the investing public. These Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the Exchange Act. As set forth herein, these Defendants, by virtue of their receipt of information reflecting the true facts regarding Tokai, his/her control over, and/or receipt and/or modification of Tokai's materially misleading misstatements and/or their associations with the Company which made

them privy to confidential proprietary information concerning Tokai, participated in the fraudulent scheme alleged herein.

97. The critical role that the success of galeterone's clinical trials played in Tokai's continued operations provides cogent evidence of fraudulent intent or recklessness. During the relevant time-period, Tokai never generated *any* revenue from *any* product sales and had incurred significant losses since inception. Galeterone was only product for which Tokai was seeking FDA approval. As a developmental stage company with a single drug candidate "in the pipeline," the pressure to make the Phase 3 trial a success was extraordinary.

98. The centrality of galeterone's successful clinical trials to Tokai's going concern created undue pressure for the Company, its management and its investment bankers to make positive statements about the progress of clinical trials and to omit to disclose negative information. The nascent development of Tokai and its having only one drug candidate in line for FDA approval provides compelling evidence that misstatements and omissions were not made in error.

99. With respect to the Registration Statement, several of the misstatements and omissions are so glaring that they provide compelling evidence of scienter. Although the Registration Statement provides that galeterone "has advantages over existing prostate cancer therapies," Tokai never conducted a Phase 2 test designed to test the effectiveness of the drug candidate on AR-V7 patients, let alone in comparison to Zytiga and Xtandi. Furthermore, Tokai did not disclose that its recent business model was prompted by an imminent article in the NEJM, or that its clinical design was faulty.

100. With respect to the public statements made after announcement of the Phase 3 clinical trials, again, glaring errors provide evidence of scienter. For a Phase 3 clinical trial to have only four viable subjects at the same time when Tokai continuously disclosed the number to be 148

simply could not have been a mistake. Significantly, the true number of test subjects was never disclosed by the Company, but by a trade organization, ASCO. Furthermore, Tokai did not disclose critical design flaws in the Phase 3 trial that were so severe that the trial could never be completed and the FDA could not have given approval to galeterone. An omission of such starkness counters an inference of non-fraudulent intent.

101. Probative evidence of scienter is comprised of Tokai's false submissions to the National Institutes of Health about the progression of Phase 3. www.ClinicalTrials.gov is a service provided by the U.S. National Library of Medicine that makes public a database of clinical trial results. Clinical study sponsors are responsible for providing accurate information and ensuring that the study follows all applicable laws. Tokai's submissions for the Phase 3 trials on www.ClinicalTrials.gov provide further evidence of scienter.[8]

102. Between May 2015 and September 27, 2017, Tokai submitted 14 updates to www.ClinicalTrials.com that concealed the failure to enroll an adequate number of test subjects. From the commencement of Phase 3 to August 22, 2016, Tokai represented that the enrollment in the Study was "148 (Anticipated)" and that the study was "Recruiting" patients. On August 22, 2016, and *after* the study was halted, Tokai updated its status to "Active, not recruiting." On January 9, 2017, Tokai updated its status to "Terminated" and represented that the enrollment in the Study was "953 (Actual)." However, it was not until June 7, 2017, that ASCO—not Tokai—disclosed that the study in fact had only 38 patients as test subjects when the study was halted. Furthermore, as stated above, because 35 of those patients "screen failed," Tokai ultimately had four eligible patients at the study's halt—not 953. Tokai clearly was hiding the failure to attract

[8] *See* https://clinicaltrials.gov/archive/NCT02438007/2015_05_07 (entries evidencing progress of the Phase 3 trial).

evaluable test subjects throughout the period of the study, and it never disclosed the true number of test subjects.

103. Tokai also submitted statements to the U.S. National Institutes of Health about the exclusion criteria for the Phase 3 study, and those statements strongly support an inference of scienter. The Phase 3 exclusion criteria were restrictive, because they reduced the number of viable test patients from 973 to four. However, the exclusion criteria listed on the www.Clinicaltrials.gov are two simple criteria that would have been apparent at the *beginning* of Phase 3:

a. Prior treatment with second generation anti-androgens (e.g. Xtandi and Zytiga); and

b. Prior treatment with chemotherapy for CRPC.

104. The Company omitted to disclose the real exclusion criteria that caused Phase 3 to fail.

105. Rampant insider selling provides evidence of scienter. This includes the CEO, CFO, COO, and a venture capital firm affiliated with one of Tokai's Directors, Novartis, which was a beneficial owner of 21.25% of Tokai's common stock:

Date	Seller	Role	Shares	Price	Proceeds
6/11/15	Novartis BioVentures Ltd.	(Affiliated Investor)	27,875	$14.20	$395,825.00
6/12/15	Novartis BioVentures Ltd.	(Affiliated Investor)	5,919	$14.20	$84,049.80
6/16/15	Novartis BioVentures Ltd.	(Affiliated Investor)	1,120	$14.27	$15,982.40
7/13/15	Novartis BioVentures Ltd.	(Affiliated Investor)	20,611	$14.202	$292,717.42
7/14/15	Novartis BioVentures Ltd.	(Affiliated Investor)	27,861	$14.41	$401,477.01
7/15/15	Novartis BioVentures Ltd.	(Affiliated Investor)	3,566	$14.258	$50,844.03
9/21/15	McBride, John S.	(Chief Operating Officer)	13,500	$14.01	$189,135.00
9/8/15	Kalowski, Lee	(Chief Financial Officer)	4,668	$13.13	$61,290.80
9/2/15	Kalowski, Lee	(Chief Financial Officer)	2,158	$12.96	$27,967.70
7/29/15	Morrison Jodie Pope	(President and CEO)	564	$13.70	$7,726.80
7/28/15	Morrison Jodie Pope	(President and CEO)	12,000	$13.70	$164,400.00
6/29/15	Morrison Jodie Pope	(President and CEO)	8,000	$13.70	$109,600.00
6/26/15	Morrison Jodie Pope	(President and CEO)	8,000	$13.83	$110,640.00

6/24/15	McBride, John S.	(Chief Operating Officer)	300	$14.20	$4,260.00
6/23/15	McBride, John S.	(Chief Operating Officer)	6,700	$14.00	$93,800.00
6/22/15	McBride, John S.	(Chief Operating Officer)	2,000	$14.02	$28,040.00
4/16/15	Kalowski, Lee	(Chief Financial Officer)	4,567	$13.00	$59,371.00
4/2/15	Kalowski, Lee	(Chief Financial Officer)	2,258	$11.45	$25,854.10

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE) (WITH RESPECT TO THE EXCHANGE ACT CLAIMS)

106. The market for Tokai's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Tokai's securities traded at artificially inflated prices during the relevant period. Plaintiff purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Tokai's securities and market information relating to Tokai, and has been damaged thereby.

107. The artificial inflation of Tokai's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff. As described herein, Tokai, Morrison, and Kalowski made or caused to be made a series of materially false and/or misleading statements about Tokai's clinical trials, business, operations, and prospects. These material misstatements and/or omissions created an unrealistically positive assessment of Tokai and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company stock. These Defendants' materially false and/or misleading statements resulted in Plaintiff purchasing the Company's securities at such artificially inflated prices.

108. At all relevant times, the market for Tokai's securities was an efficient market for the following reasons:

a. Tokai stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, Tokai filed periodic public reports with the SEC and/or the NASDAQ;

c. Tokai regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d. Tokai was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

109. As a result of the foregoing, the market for Tokai's securities promptly digested current information regarding Tokai from all publicly available sources and reflected such information in Tokai's stock price. Under these circumstances, Plaintiff suffered injury through his purchase of Tokai's securities at artificially inflated prices and a presumption of reliance applies.

110. In addition to relying on the integrity of market pricing for Tokai shares, Plaintiff relied on the statements by the Company and its agents detailed herein.

NO SAFE HARBOR

111. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false or misleading statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then existing facts and conditions. In addition, to the extent that certain of the statements alleged to be false or misleading may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe

harbor is determined to apply to any forward-looking statements pleaded herein, the Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Tokai who knew that the statement was false when made.

COUNT I

For Violations of Section 11 of the Securities Act of 1933 (Against All Defendants)

112. Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 111 above as if fully set forth herein.

113. This Cause of Action is brought pursuant to § 11 of the Securities Act, 15 U.S.C. § 77k, against all Defendants. This claim does not sound in fraud. For purposes of this Section 11 claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a claim under Section 11 of the Securities Act of 1933. This claim is based solely on strict liability as to Tokai, and negligence as to the remaining Defendants.

114. The Registration Statement was materially false and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein. Defendant Tokai is strictly liable to Plaintiff for the misstatements and omissions. None of the other Defendants named herein made a reasonable investigation or possessed reasonable grounds or the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

115. The Individual Defendants either signed the Registration Statement directly (or under the Power of Attorney with Defendant Morrison), and the Underwriter Defendants underwrote the securities issued pursuant to the Registration Statement.

116. By reason of the conduct herein alleged, each Defendant named herein violated, and/or controlled a person who violated, Section 11 of the Securities Act.

117. Plaintiff acquired Tokai common stock traceable to the IPO. Because this was Tokai's first and only IPO, all shares purchased by Plaintiff are traceable to the IPO. According to the Registration Statement at 146, "[p]rior to this offering, there has been no public market for our common stock. . . ."

118. Plaintiff has sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to these Defendants' violations.

119. At the time of Plaintiff's purchases of Tokai common stock, Plaintiff was without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein.

COUNT II

For Violations of Section 12(a)(2) of the Securities Act of 1933 (Against Defendants Tokai, Morrison, and the Underwriter Defendants)

120. Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 119 above as if fully set forth herein. This claim is asserted against Tokai, Morrison and the Underwriter Defendants. This claim does not sound in fraud. For purposes of this Section 12(a)(2) claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a claim under Section 12(a)(2) of the Securities Act of 1933. This claim is based solely on negligence. By means of the defective Prospectus and other statements, these Defendants promoted and sold Tokai stock to Plaintiff.

121. The Prospectus and other Statements contained untrue statements of material fact, and/or concealed or failed to disclose material facts, as detailed below. The Defendants owed Plaintiff who purchased Tokai common stock pursuant to the Prospectus and other Statements the duty to make a reasonable and diligent investigation of the statements contained therein to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. These Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus and other Statements as set forth below.

122. The Prospectus was incorporated by reference into the Registration Statement. In addition, the Prospectus contains many material misstatements and omissions that are the same as, or similar to the ones found in the Registration Statement.

1. Misleading Statements about Preliminary Data and Number of Test Subjects

123. The Prospectus states: "In clinical studies conducted by researchers at MD Anderson Cancer Center and Johns Hopkins University, the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga® (abiraterone acetate) and Xtandi® (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion."

124. As set forth above, this statement is misleading, because it does not disclose that the leaders of the referenced studies stated that "limited patient numbers warrant further validation" and "[n]ow that was a small pilot trial for about 62 patients," which limits the reliability of those findings. The statement is further misleading because it references 2013 sales of $2.1 billion for the Incumbent Medications, but omits to state that their Phase 3 trials involved over 2,000 test subjects, not 148.

2. Misleading Statements About Conflicted Researchers

125. The Prospectus states: "In May 2014, we announced interim data from our ARMOR2 trial at The American Society of Clinical Oncology 2014 Annual Meeting, or ASCO." It continues: "In addition, we presented data from a retrospective subset analysis in which four treatment-naïve CRPC patients in ARMOR2 were identified as having truncated androgen receptors with C-terminal loss. All four of these patients had maximal reductions in PSA levels of at least 50%."

126. As a threshold matter the ASCO Meeting Library abstract for the Tokai presentation on May 31, 2014, makes no reference to a retrospective subset analysis of four AR-V7 patients. Moreover, the presentation was made by Dr. Bruce Montgomery. Although Tokai publicly references Dr. Montgomery's affiliation as "Professor, Medical Oncology Division, University of Washington School of Medicine and a lead investigator of ARMOR2," Dr. Montgomery had an undisclosed financial relationship with Tokai.

3. Misleading Statements about FDA Discussions

127. The Prospectus states: "In August 2014, we met with the FDA to discuss our plans for a pivotal Phase 3 clinical trial to support initial new drug approval by the FDA. Based on these discussions, we expect that our ARMOR3-SV trial will be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant."

128. This statement was materially misleading, because it does not provide any mention of the exclusion criteria for participants in the study. It is a reasonable inference that the exclusion criteria was a material topic of discussion between Tokai and the FDA due to the extraordinary result of the Phase 3 trial was that all test subjects were excluded but for four patients.

129. For the same reasons as alleged above with respect to the Registration Statement, the Prospectus was misleading, notwithstanding the many warnings about what *could* occur in the Phase 3 trial of galeterone set forth in the Risk Factors, because it did not disclose that galeterone had *no* reasonable chance of being approved by the FDA.

130. First, prior to the filing the Prospectus, Tokai never conducted a Phase 2 trial designed to test the effectiveness of galeterone on AR-V7 patients. Nor did it run a comparative trial designed to test the drug's effectiveness against Zytiga and Xtandi. Instead, the Company merely ran a Phase 2 trial testing galeterone for effectiveness in CRPC prostate cancer, evaluating 51 treatment-naïve cancer patients classified as CRPC.

131. Lacking any reasonable basis to contend that galeterone is more effective, if at all, than Zytiga or Xtandi, and aware that the "NEJM Article" would eminently report that Zytiga and Xtandi were not effective in AR-V7 patients, the Defendants conducted an after-the-fact analysis of Tokai's Phase 2 trial, which they called "retrospective subset analysis," to be able to represent in the Registration Statement that: (1) Tokai's focus was on AR-V7; (2) four out of the 51 patients in the study had AR-V7; and (3) galeterone was effective in all four of those patients.

132. Tokai was aware of the upcoming publication of the NEJM Article because one of its authors—Dr. Mario Eisenberger—was also a lead contributor to the Phase 2 trial.

133. That the material change of Tokai's business model was driven by the eminent publication of the NEJM Article is evident from a review of the Company's preliminary and final registration statements, each iteration placing greater and more frequent emphasis on AR-V7. Moreover, while the final Registration Statement said that galeterone was effective in six of seven AR-V7 patients, an earlier draft represented that "four patients were identified as having

altered androgen receptors that were truncated, all of whom showed clinically meaningful PSA reductions of at least 50%."

134. Accordingly, Tokai's business model, prospects and clinical trial results were materially revised shortly before the filing of the Registration Statement, in order to differentiate galeterone from existing products and induce investors to purchase Tokai shares. The Prospectus failed to disclose that Tokai never conducted a Phase 2 trial designed to test the effectiveness of galeterone on AR-V7 patients; that the Company had materially changed its focus shortly before the IPO; that the six AR-V7 patients who showed improvement had very recently been only four; and that its business model was actually predicated on a to-be-published NEJM Article. These facts were material to investors because they would have reasonably concluded that the Company was going public with no viable business plan.

135. Second, Tokai's design of galeterone's Phase 3 trial was flawed and virtually guaranteed to fail. Tokai was embarking on its Phase 3 trial blind, as no prior testing had been done to measure the drug's effectiveness in AR-V7 patients and the very structure of its Phase 3 test was woefully inadequate.

136. As an initial matter, the FDA typically requires the successful completion of two well-controlled clinical trials involving 300 to 3,000 volunteers, to support approval. In the case of galeterone, however, Tokai planned only a *single* trial involving 170 patients. (For comparative purposes, the Phase 3 study size for Xtandi involved 1,199 patients; the study for Zytiga involved 1,195 patients).

137. To make matters worse, galeterone's Phase 3 trial was unprecedented. Tokai abandoned its Phase 2 trial design and formulated an entirely new trial design with two principal characteristics: (i) whereas the Phase 2 trial was evaluating galeterone as a stand-alone drug,

Tokai designed its Phase 3 trial to compare galeterone specifically to Xtandi; and, (ii) whereas the Phase 2 trial used a decreased PSA level as an endpoint, Tokai changed its endpoint to be radiographic progression free survival ("PFS"). Thus, not only did Tokai change the very subject of the test, but also how success would be measured.

138. Tokai had no idea what outcome to expect from the Phase 3 trial since the test group and endpoint were so changed that it was as if no Phase 2 trial had ever been completed.

139. Plaintiff did not know, nor in the exercise of reasonable diligence could have known, of the untruths and omissions contained in the Prospectus and other Statements at the time Plaintiff acquired Tokai common stock.

140. Plaintiff acquired Tokai common stock traceable to the IPO. Because this was Tokai's first and only IPO, all shares purchased by Plaintiff are traceable to the IPO. According to the Registration Statement at 146, "[p]rior to this offering, there has been no public market for our common stock . . . ."

141. By reason of the conduct alleged herein, Defendants violated section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiff purchased Tokai common stock pursuant to the Registration Statement sustained substantial damages in connection with their purchases of the stock.

142. Plaintiff, who has sold his common stock, seeks damages to the extent permitted by law.

COUNT III

For Violations of Section 15 of the Securities Act of 1933 (Against Defendants Morrison and Kalowski)

143. Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 142 above as if fully set forth herein.

144. This claim is asserted against Defendants Morrison and Kalowski.

145. This claim does not sound in fraud. For the purposes of this Section 15 claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a claim under Section 15 of the Securities Act of 1933. This claim is based solely on the control of Defendants who violated Section 11 and 12 of the Securities Act.

146. Defendants Morrison and Kalowski each were control persons of Tokai by virtue of their positions as C.E.O. and C.F.O. of Tokai, respectively, and who signed the Registration Statement.

147. Defendants Morrison and Kalowsi each were culpable participants in the violations of Sections 11 and 12 of the Securities Act alleged in Count One and Count Two above, based on their having signed or authorized the signing of the Registration Statement, assistance in disseminating the Prospectus and having otherwise participated in the process which allowed the IPO to be successfully completed.

COUNT IV

For Violation of Section 10(b) of The Exchange Act and Rule l0b-5 Promulgated Thereunder Against Defendants Tokai, Morrison, Kalowski

148. Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 147 above as if fully set forth herein.

149. Defendants Tokai, Morrison, and Kalowski carried out a plan, scheme and course of conduct which was intended to and, throughout the relevant time period, did: (i) deceive the investing public, including Plaintiff, as alleged herein; and (ii) cause Plaintiff to purchase Tokai's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, these Defendants, and each of them, took the actions set forth herein.

150. Defendants Tokai, Morrison, and Kalowski (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts

necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Tokai's securities in violation of Section 10(b) of the Exchange Act and Rule l0b-5.

151. Defendants Tokai, Morrison, and Kalowski, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Tokai's financial well-being and prospects, as specified herein.

152. Defendants Tokai, Morrison, and Kalowski employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Tokai's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Tokai and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities.

153. Defendants Morrison and Kalowski’s primary liability, and controlling person liability arises from the following facts: (i) these Defendants were high-level executives at the Company during the relevant time period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of their responsibilities and activities as a senior officer of the Company, was privy to and participated in the creation, development and reporting

of the Company's internal budgets, plans, projections and/or reports; (iii) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances and operations at all relevant times; and (iv) each of these Defendants was aware of the Company's dissemination of information to the investing public, which they knew and/or recklessly disregarded, was materially false and misleading.

154. The Defendants Tokai, Morrison, and Kalowski had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Tokai's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by overstatements and/or misstatements of the Company's business, operations, financial well-being, Defendants Tokai, Morrison, and Kalowski, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

155. The leading misrepresentation and omission is the failure to disclose the *lack of test subjects*. When the Phase 3 trial was halted, the study did not have 148 test patients—but only four.

156. The Company and Defendants Morrison and Kalowski made other material misstatements and omissions of fact:

a. They overstated the percentage of patients having the AR-V7 gene variant among prostate cancer patients;

b. They omitted to state that the studies showing the ineffectiveness of the incumbent medications in AR-V7 patients were not reliable, and that fact was even admitted by the proponents of those studies;

c. Although they disclosed that the two incumbent medications had annual sales of $1.7 billion and $445 million, they failed to disclose that the clinical studies supporting FDA approval of those medications involved 1,195 and 1,199 test patients, respectively (versus a putative 177 test patients);

d. Of conclusions that could be drawn from the Phase 3 study, an undisclosed finding was that the incumbent medications were actually more effective than the Company's drug candidate for treating AR-V7 patients;

e. They did not disclose that six of the eight scientists touting the effectiveness of the drug candidate in the Phase 2 studies in the May 2016 *Journal of Oncology* article had financial connections to the Company;

f. They did not disclose that both Co-Principal Investigators running the Phase 3 trial had financial connections with the Company;

g. They did not accurately disclose Company's communications with the FDA. These communications included the negotiation of exclusion criteria which caused all but four of the test subjects to "screen fail" (be excluded from the study);

h. They did not disclose that the Company changed strategy for use of the IPO proceeds in the eleventh hour from completing the Phase 2 Study to initiating a "pivotal" Phase 3 Study; and

i. These Defendants Tokai, Morrison, and Kalowski repeatedly made misleading submissions to the public on a web-site sponsored by the National Institutes of Health, www.ClincalTrials.gov. First, before the Phase 3 was halted, the Company repeatedly stated that it anticipated 148 test subjects, when in fact, the largest number of subjects in the Phase 3 trial was 38. Second, the Company listed on www.ClinicalTrials.gov only two of multiple exclusion criteria that caused 34 of the 38 test subjects to "screen fail" when the Phase 3 trial was halted.

157. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Tokai's securities was artificially inflated during the relevant period of time. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants Tokai, Morrison, and Kalowski or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by these Defendants, but not disclosed in public statements by them, Plaintiff acquired Tokai's securities at artificially high prices and were damaged thereby.

158. At the time of said misrepresentations and/or omissions, Plaintiff was ignorant of their falsity, and believed them to be true. Had Plaintiff and the marketplace known the truth regarding the problems that Tokai was experiencing, which were not disclosed by Defendants,

Plaintiff would not have purchased or otherwise acquired their Tokai securities, or, if he had acquired such securities, he would not have done so at the artificially inflated prices which he paid.

159. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

160. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered damages in connection with his respective purchases and sales of the Company's securities.

COUNT V

For Violation of Section 20(a) of The Exchange Act against Defendants Morrison and Kalowski

161. Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 160 above as if fully set forth herein.

162. The Defendants Morrison and Kalowski acted as controlling persons of Tokai within the meaning of Section 20(a) of the Exchange Act as Chief Executive Officer and Chief Financial Officer, respectively. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements that Tokai filed with the SEC and disseminated to the investing public; Defendants Morrison and Kalowski had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements, which Plaintiff contends are false and misleading. Defendants Morrison and Kalowski were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

163. In particular, Defendants Morrison and Kalowski had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

164. As set forth above, Tokai violated Section 10(b) and Rule l0b-5 by its acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants Morrison and Kalowski are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants Morrison and Kalowski's wrongful conduct, Plaintiff suffered damages in connection with their purchases of the Company's securities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Awarding compensatory damages in favor of Plaintiff and against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, but not less than $10,835,724, including interest thereon;

B. Awarding Plaintiff his reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

C. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38, Plaintiff hereby demands a trial by jury of all issues triable by jury.

Dated: September 7, 2018

OLSHAN FROME WOLOSKY LLP

By: */s/ John G. Moon*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the within First Amended Complaint was served electronically upon the parties through the Court's CM/ECF system pursuant to Local Rule 5.2(b)

Dated: September 7, 2018

Respectfully submitted,

OLSHAN FROME WOLOSKY LLP

By: /s/John G. Moon

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